

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

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on April 5, 2007Signature Typed or printed name Travis M. Wohlers

Application Number

10/511,882

Filed

10/19/04

First Named Inventor

Bodo Kulkinski

Art Unit

1657

Examiner

L. Schuberg

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

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applicant/inventor.

☐

assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

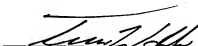
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attorney or agent of record.

Registration number 57,423☐

attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 _____



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Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

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*Total of _____ forms are submitted.

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ARGUMENTS IN SUPPORT OF PRE-APPEAL BRIEF REQUEST FOR REVIEW
FOR APPLICATION SERIAL NUMBER 10/511,882

The present obviousness rejection over Fuchs *et al.* (WO 01/97634) should be withdrawn because it is factually and legally unsupported.

Fuchs notes the importance of highly unsaturated fatty acids in a number of biological processes including prostaglandin metabolism, the heart and vascular system, carbohydrate metabolism, obesity, skin metabolism, hormonal metabolism, the performance of the central nervous system, the lungs, the joints, the immune system, autoimmune disorders, and the aging process (Fuchs, p. 3) (pages are numbered according to the numbering in the translation of WO 01/97634 provided with the Office Action dated May 11, 2006). Also noted by Fuchs is that the dosage requirement for highly unsaturated fatty acids is in the gram range (Fuchs, p. 4). Fuchs indicates that milk dried on the matrix is insufficient to provide the required dosage of highly unsaturated fatty acids (Fuchs, p. 15). Rather, the high levels of highly unsaturated fatty acids are provided by plant and fish oils (Fuchs, p. 3-4; p. 13). According to Fuchs, the benefits of adding milk are its “immunostimulating effects on the human and animal organism” (Fuchs, p. 15) and its effect on shelf life or flavor (Fuchs, p. 18).

Thus, while Fuchs may disclose the importance of products enriched with highly unsaturated fatty acids for clinical nutrition medicine of various conditions including neurodermatitis or psoriasis, Fuchs does not provide any teaching or suggestion of a method of treating or preventing neurodermatitis or psoriasis in a subject by administering to the subject a composition comprising a mare milk concentrate dried on a biologically inert, disperse matrix. In fact, Fuchs indicates that milk is insufficient to provide an adequate dosage of highly unsaturated fatty acids (*see* Fuchs, p. 15).

The Examiner’s representation of the teachings of Fuchs are factually inaccurate. For example, on page 4 of the final Office Action, the Examiner states that “[o]ne of ordinary skill in

the art would have been motivated to use the composition of Fuchs for the treatment and prevention of dry skin diseases such as neurodermatitis and psoriasis since the highly unsaturated fatty acids in the composition are taught by Fuchs to be important for skin metabolism and these skin disorders (p. 3).” Similarly, on page 5 of the final Office Action the Examiner states: “Fuch’s [sic] statement that ‘these (highly) unsaturated fatty acids are very important in biological and clinical nutrition medicine, especially for...the skin metabolism (neurodermatitis, psoriasis)...’ (page 3) clearly shows the intention of using the reference composition in the treatment of these specific skin diseases.” As discussed above, Fuchs’ reference to highly unsaturated fatty acids is in regard to those provided by plant and fish oils. Milk is not disclosed as providing (highly) unsaturated fatty acids for the treatment of any disease, much less skin disease. Fuchs only teaches that in certain embodiments, milk may be added to the matrix and fatty acid mixture for its immunostimulating effects (Fuchs, p. 15) and its effect on shelf life or flavor (Fuchs, p. 18).

In fact, since neurodermatitis and psoriasis are regarded as autoimmune diseases disorders resulting from an over-reactive immune response (*see e.g.*, Specification, p. 2, ln. 9-13 and p. 5, ln. 8-13), a person of ordinary skill in the art would not have been motivated to use nor have had a reasonable expectation of success in a method of treating or preventing neurodermatitis or psoriasis in a subject by orally administering a composition comprising a mare milk concentrate dried on a biologically inert, disperse matrix to the subject, in view of the disclosure in Fuchs that a dried, mare milk concentrate has immunostimulatory properties.

For the reasons set forth above, the Examiner failed to establish a *prima facie* case of obviousness because the Examiner failed to show (1) that Fuchs teaches or suggest all of the limitations of the current claims, (2) that there is a suggestion or motivation to modify the

teachings of Fuchs, and (3) that there is a reasonable expectation of success. Applicant, therefore, requests the withdrawal of this rejection.